

2960-136WO

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

BROMBERG & SUNSTEIN LLP

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/136WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. PCT/US2007/061681	International filing date (day/month/year) 06/02/2007	(Earliest) Priority Date (day/month/year) 06/02/2006
Applicant CONFORMIS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- the international application in the language in which it was filed
- a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. Certain claims were found unsearchable (See Box No. II)

3. Unity of invention is lacking (see Box No III)

4. With regard to the title,

- the text is approved as submitted by the applicant
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 26W
 - as suggested by the applicant
 - as selected by this Authority, because the applicant failed to suggest a figure
 - as selected by this Authority, because this figure better characterizes the invention
- b. none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/061681

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/15 ADD. A61B17/16 A61B17/17 A61B19/00 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 154 717 A (MATSEN III FREDERICK A [US] ET AL) 13 October 1992 (1992-10-13) abstract; figures 16-18 column 22, lines 56-64 column 23, lines 14-28 -----	1,6-11, 56-60, 91,93
X	US 6 344 043 B1 (PAPPAS MICHAEL J [US]) 5 February 2002 (2002-02-05) abstract; figures 6-9 -----	1-14, 56-60, 91,93
X	US 2005/085920 A1 (WILLIAMSON RICHARD V [US]) 21 April 2005 (2005-04-21) abstract paragraphs [0088], [0091] -----	1,6-11, 56-60, 91,93
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family		
Date of the actual completion of the international search 31 August 2007		Date of mailing of the international search report 07/09/2007
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

International application No.
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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 15-55, 61-90, 92, 94-132
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/061681

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5154717	A	13-10-1992	NONE
US 6344043	B1	05-02-2002	NONE
US 2005085920	A1	21-04-2005	NONE

PATENT COOPERATION TREATY

From the
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To: <p style="text-align: center;">see form PCT/ISA/220</p>	<p style="text-align: center;">WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)</p>
Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)	

Applicant's or agent's file reference see form PCT/ISA/220	FOR FURTHER ACTION See paragraph 2 below
---------------------------------------------------------------	----------------------------------------------------

International application No. PCT/US2007/061681	International filing date (day/month/year) 06.02.2007	Priority date (day/month/year) 06.02.2006
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International Patent Classification (IPC) or both national classification and IPC
 INV. A61B17/15
 ADD. A61B17/16 A61B17/17 A61B19/00

Applicant
 CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Macaire, Stéphane Telephone No. +31 70 340-3115
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - on paper
 - in electronic form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in electronic form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- the entire international application
- claims Nos. 15-55,61-90,92,94-132

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- no international search report has been established for the whole application or for said claims Nos. 15-55,61-90,92,94-132
- a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/061681

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>10,14,57</u>
	No: Claims	<u>1-9,11-13,56,58-60,91,93</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-14,56-60,91,93</u>
Industrial applicability (IA)	Yes: Claims	<u>1-14,56-60,91,93</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Re Item V.

1 Reference is made to the following documents:

D1 : US 5 154 717 A (1992-10-13)

D2 : US 6 344 043 B1 (2002-02-05)

2 INDEPENDENT CLAIMS 1, 12, 13, 14, 56, 91 and 93

2.1 [claim 1] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document):

a system (figs. 16-18) for joint arthroplasty (abstract), the system comprising:

- a first template (200), the first template including:

at least one surface for engaging a first surface of a joint (211, 212), the surface being a mirror image of portions or all of the first surface (fig. 17); and

at least one guide (207) for directing movement of a surgical instrument; and

- a linkage(201) for cross-referencing at least one surgical tool relative to said guide and relative to one of an anatomical and a biomechanical axis.

2.2 [claim 12] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 12 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this document):

A system for joint arthroplasty (fig. 7), the system comprising:

- a first template (12), the first template including:

at least one surface for engaging a first surface of a joint, the surface being a mirror image of portions of the first surface (fig. 7); and

at least one guide (40, 16, 18A) for directing movement of a surgical instrument; and

- a linkage(42) for cross-referencing at least one surgical tool on a second surface of the joint opposing the first surface (figs. 8, 12).

2.3 [claim 13] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 13 is not new in the sense of Article 33(2) PCT.

Document D2 also discloses (the references in parentheses applying to this document):

- a second template (98), the second template including:

at least one second template surface for engaging a second surface of a joint, the second template being a mirror image of portions or all of the second surface (fig. 8); and

at least one guide (16) for directing movement of a surgical instrument; and

- a linkage (42) for cross-referencing the first template and the second template (fig. 8).

2.4 [claim 14] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 14 does not involve an inventive step in the sense of Article 33(3) PCT.

The subject-matter of claim 14 differs from the device known from D2 in that: the linkage allows for rotation relative to one of an anatomical and a biomechanical axis.

The problem to be solved by the present invention is to allow a trial movement of the joint with the two templates in position before the arthroplasty.

The possible rotation is merely one of several straightforward possibilities from which the skilled person would select, in order to build a joint arthroplasty system, without the exercise of inventive skill, in order to solve the problem posed.

2.5 [claim 56] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 56 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this document):

a surgical tool comprising:

a template (figs. 1, 6, 7, 9) including:

a surface for engaging a joint surface, the surface being a mirror image of a portion or all of the joint surface (fig. 7); and

two or more guides (36, 42 ...) for directing movement of a surgical instrument, wherein the shape and/or position of at least one of the guides (36) is based, at least in part, on at least one axis related to said joint (femoral axis).

2.6 [claim 91] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 91 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

A template (fig. 8) comprising:

at least one contact surface for positioning onto a surface of a joint, the contact surface at least partially being a mirror image of an interface between an arthritic and a normal portion of the joint surface, a guide for directing movement of a surgical instrument.

2.7 [claim 93] The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 93 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

A template (fig. 8) comprising:

at least one contact surface for positioning onto a surface of a joint, the contact surface at least partially being a mirror image of a normal portion of the joint surface, a guide for directing movement of a surgical instrument.

3 DEPENDENT CLAIMS 2-11, 57-60

Dependent claims 2-11, 57-60 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Re Item VIII

Certain observations on the international application

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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The application does not meet the requirements of Article 6 PCT, because the claims is not clear.

The subject matter of the independent claims is defined with reference to the surface of a bone. The kind of bone (hip, knee, shoulder, foot) is not specified and the bone not part of the device claimed. Additionally, the shape and size of a bone depend of the patient. Thus, the intended limitations are therefore not clear from the claims.